

## **REMARKS**

Claims 61, 63, 67, 68, 76, 77, 79 have been amended. Claims 1-60, 65, 66, and 75 have been cancelled without prejudice. The foregoing amendments are taken in the interest of expediting prosecution and there is no intention of surrendering any range of equivalents to which Applicant would otherwise be entitled in view of the prior art.

The undersigned would like to thank the Examiner for the courtesies extended at the in-person interview on February 27, 2008. At that interview, a proposed amendment was discussed to further clarify the structure of the present invention. The new rejections (and the items upon which they were based) also were discussed.

Based upon the interview, Applicant has amended the claims to more positively recite the claimed combination that includes (among other features) an improved clip for marking a biopsy site or the site of an aspirated cyst during a radiographic analysis, the clip extending along an axis between a first end and a second end and comprising a deformable metal structure that has an apex disposed along the clip axis and defining where the first and second arc segments converge, that penetrates breast tissue, and that has a deformable metal structure configured so that it is compressed to reside entirely within the delivery tube, it deploys through the delivery device, and in both an original pre-deployment state and a post-deployment state the first ends of the first and second arc segments project in a direction outward relative to the clip axis opposite to that of the second ends of the first and second arc segments, the first ends of the first and second arc segments project in a direction generally away from the second ends of the first and second arc segments. By virtue of the claimed structure, the clip penetrates breast tissue upon deformation of the segments relative to the clip axis after being driven through the exit opening of the delivery tube of the breast biopsy device, and substantially prevent migrations of the deployed clip.

As was pointed out at the interview, basis for this amendment can be found throughout the specification and claims as originally filed, including (without limitation) in the drawings of Figs. 1, 3, 7, 8, 11C, 13A, 13B, 15, 16G, 16I, 16J, and following paragraph (corresponding to paragraph 59 in the published application No. US 2004/0097981):

Preferably the stored energy of a clip as it resides (e.g., in a compressed state relative to its relaxed state) within the clip delivery device prior to deployment is sufficient that it can unfold upon itself and **penetrate tissue** in the absence of an externally applied force, as is common with prior clip devices, such as FIG. 2A (which generally employs a detachable tensioning wire). Nonetheless, the shape of the clip is such that uncontrollable spiraling, which might lead to **undesired migration can be avoided**. (emphasis added).

See also paragraph corresponding to paragraph 60 in the published application No. US 2004/0097981:

Accordingly, as the wire of the clip progresses to its relaxed state, upon exiting the delivery device 110, it is capable of pulling the clip 120 by itself (i.e., under its own stored energy and preferably in the absence of additional user-applied energy) into position, assuring secure deployment and substantially preventing migration. (emphasis added).

As was discussed at the interview, the Ainsworth publication (US 2002/0165561A1) does not teach, suggest or motivate the person skilled in the art to modify its teachings to arrive at the claimed combination. Foremost, the structures of Ainsworth are design to clamp tissue together, and to spread a clamping load across an area of tissue. The ends of the clip are blunted so that this can occur. The modification of the Ainsworth clips to arrive at the Applicant's claimed invention would defeat the purpose of Ainsworth, which seeks to avoid tissue penetration. See *In re Ratti*, 270 F.2d 810, 123 U.S.P.Q. 349 (CCPA 1959). See also *In re Fritch*, 23 U.S.P.Q.2d 1780, 1783-84 (Fed. Cir. 1992).

Additionally, it can be seen that the pre- and post-deployment configurations of Ainsworth have the ends of the clip facing each other. As presently claimed, such structure does not arise in the Applicant's clip, in which the ends project outwardly and away from opposing ends.

Also believed to be of significance is the claim language that distinguishes the manner in which the Ainsworth clip must be deployed. There is no teaching that the Ainsworth clip resides entirely within a tube or could be deployed by being driven through a tube. Rather, it appears essential for its operation that only half of the clip be deformed for deployment.

In short, especially as presently amended, the pending claims are believed to patentably distinguish over the prior art of record. Withdrawal of the rejection is therefore respectfully requested.

Further, it is believed improper to engage in a hindsight analysis, attempting to use the present claims as a roadmap to analyze the prior art. *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999). In the case of *In re Rouffet*, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998), the Federal Circuit recognized the risk inherent in such an approach and explained:

As this court has stated, "virtually all [inventions] are combinations of old elements." *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 698, 218 USPQ 865, 870 (Fed. Cir. 1983); see also *Richdel, Inc. v. Sunspool Corp.*, 714 F.2d 1573, 1579-80, 219 USPQ 8, 12 (Fed. Cir. 1983) ("Most, if not all, inventions are combinations and mostly of old elements."). Therefore an examiner may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention. Such an approach would be "an illogical and inappropriate process by which to determine patentability." *Sensonics, Inc. v. Aerosonic Corp.*, 81 F.3d 1566, 1570, 38 USPQ2d 1551, 1554 (Fed. Cir. 1996). To prevent the use of hindsight

based on the invention to defeat patentability of the invention, this court requires the examiner to show a motivation to combine the references that create the case of obviousness. In other words, the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.

In short, the claimed invention is nonobvious. Withdrawal of the rejection is therefore respectfully requested.

By the present amendment, it does not follow that the amended claims have become so perfect in their description that no one could devise an equivalent. After amendment, as before, limitations in the ability to describe the present invention in language in the patent claims naturally prevent the Applicants from capturing every nuance of the invention or describing with complete precision the range of its novelty or every possible equivalent. See, Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 62 USPQ2d 1705 (2002). Accordingly, the foregoing amendments are made specifically in the interest of expediting prosecution and there is no intention of surrendering any range of equivalents to which Applicants would otherwise be entitled. Statements made by Applicant that are inconsistent with those presented herein or that otherwise delimit the claims beyond that necessary to secure allowance are hereby retracted.

#### **Election of Species Clarification**

As also was discussed at the interview, for sake of clarity, the species election should be amended to include within the elected species the embodiments of Figs. 16G, 16I and 16J. For purposes of the present Amendment all three embodiments have been treated as within the elected species.

#### **Supplemental Information Disclosure Statement**

Applicant includes herewith a Supplemental Information Disclosure Statement for consideration and respectfully requests consideration of same.

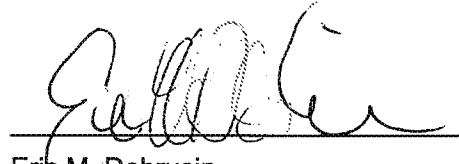
#### **CONCLUSIONS**

In view of Applicant's remarks, the Examiner's previously presented rejections are believed to be rendered moot. Accordingly, Applicant submits that the present application is in condition for allowance and requests that the Examiner pass the case to issue at the earliest convenience. Should the Examiner have any question or wish to further discuss this application, Applicant requests that the Examiner contact the undersigned at (248) 292-2920.

If for some reason Applicant has not requested a sufficient extension and/or have not paid a sufficient fee for this response and/or for the extension necessary to prevent the abandonment of this application, please consider this as a request for an extension for the required time period and/or authorization to charge Deposit Account No. 50-1097 for any fee which may be due.

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